

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Soo-Hyun Kim *et al.*
Serial No.: 10/578,943
Filed: 11/09/2006
Entitled: **Compositions And Methods For Regulation Of Tumor Necrosis Factor-Alpha**

Group No.: 1647
Examiner:



INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being facsimile transmitted to the USPTO or is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: March 5, 2008

By: _____

Cliff Cannon-Cin

Dear Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application.

The following citations are referred to in the body of the Specification:

- U.S. Patent No. 6,277,969 to Le *et al.*, "Anti-TNF Antibodies And Peptides Of Human Tumor Necrosis Factor," 2001;
- U.S. Patent No. 6,448,380 to Rathjen *et al.*, "Tumor necrosis factor antibodies," 2002;
- Banda *et al.*, "Mechanisms of effects of complement inhibition in murine collagen-induced arthritis," *Arthritis Rheum*, 46:3065, 2002;
- Banda *et al.*, "Mechanisms of inhibition of collagen-induced arthritis by murine IL-18 binding protein," *J Immunol*, 170:2100-2105, 2003;

- Bendele *et al.*, "Combination benefit of treatment with the cytokine inhibitors interleukin-1 receptor antagonist and PEGylated soluble tumor necrosis factor receptor type I in animal models of rheumatoid arthritis," *Arthritis Rheum*, 43:2648-2659, 2000;
- Bernot *et al.*, "A transcriptional map of the FMF region" *Genomics*, 50:147-160, 1998;
- Cohen, "Systemic Autoimmunity," in Paul (ed.) Fundamental Immunology, Lippincott-Raven Publishers: Philadelphia, pp. 1067-1088, 1999;
- Dahl *et al.*, "Identification of a novel gene expressed in activated natural killer cells and T cells," *J Immunol*, 148:597-603, 1992;
- Davis *et al.*, "Treatment of rheumatoid arthritis with PEGylated recombinant human soluble tumour necrosis factor receptor type I: a clinical update," *Ann Rheum Dis*, 59Suppl1:i41-3, 2000;
- Faggioni *et al.*, "IL-18-binding protein protects against lipopolysaccharide- induced lethality and prevents the development of Fas/Fas ligand-mediated models of liver disease in mice," *J Immunol*, 167:5913-5920, 2001;
- Firestein, "Rheumatoid Arthritis," in Scientific American Medicine, 2000;
- Gracie *et al.*, "A proinflammatory role for IL-18 in rheumatoid arthritis," *J Clin Invest*, 104:1393-1401, 1999;
- Panelli *et al.*, "Gene-expression profiling of the response of peripheral blood mononuclear cells and melanoma metastases to systemic IL-2 administration" *Genome Biol*, 3(7):research0035.1-0035.17, 2002; and
- Steed *et al.*, "Inactivation of TNF signaling by rationally designed dominant-negative TNF variants," *Science*, 301:1895-1898, 2003.

The following references were cited in the International Search Report of the parent International Application No. PCT/US2004/037578 (our file UTCA-08870):

- International Publication No. WO 02/059260 of Tang *et al.*, "Novel nucleic acids and polypeptides," 2002, provided by WIPO; and
- Neto *et al.*, "Shotgun sequencing of the human transcriptome with ORF expressed sequence tags," *Proc Natl Acad Sci USA*, 97:3491-3496, 2000.

Additionally, Applicants have become aware of the following references, which may be material to patentability of the invention:

- U.S. Patent No. 6,572,852 to Smith *et al.*, “Method for suppressing inflammatory responses by administering TNFR,” 2003;
- U.S. Patent No. 6,706,491 to Chang *et al.*, “Reagents and methods for identifying and modulating expression of genes regulated by P21,” 2004;
- U.S. Patent No. 6,989,262 to Bejanin *et al.*, “Plasmin variants and uses thereof,” 2006;
- Publication No. US 2003/0087270 of Schlegel *et al.*, “Novel genes, compositions, kits and methods for identification, assessment, prevention, and therapy of cervical cancer,” 2003;
- Publication No. US 2003/0092616 of Matsuda *et al.*, “STAT6 activation gene,” 2003;
- Publication No. US 2003/0148316 of Lipford *et al.*, “Methods and compositions relating to plasmacytoid dendritic cells,” 2003;
- Publication No. US 2003/0154032 of Pittman *et al.*, “Methods and compositions for diagnosing and treating rheumatoid arthritis,” 2003;
- Publication No. US 2005/0048490 of Azimzai *et al.*, “Proteins associated with cell growth, differentiation and death,” 2005;
- Publication No. US 2005/0130145 of Yue *et al.*, “Secreted proteins,” 2005;
- Publication No. US 2005/0208496 of Ohtani *et al.*, “Methods of testing for bronchial asthma or chronic obstructive pulmonary disease,” 2005;
- Publication No. US 2006/0088532 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” 2006;
- International Publication No. WO 01/64886 of Gaiger *et al.*, “Compositions and methods for the detection, diagnosis and therapy of hematological malignancies,” 2001, cover page of 1252 page document provided, complete document will be provided at the Examiner’s request;
- International Publication No. WO 02/083898 of Bejanin *et al.*, “Full-length human cDNAs encoding potentially secreted proteins,” 2002, cover page of 735 page document provided, complete document will be provided at the Examiner’s request;


- International Publication No WO 02/096943 of Honda *et al.*, “STAT6-activating genes,” 2002, cover page of Japanese document provided, with US 2003/0092616 listed as English translation;
- International Publication No. WO 03/080640 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” 2003;
- International Publication No. WO 2005/016962 of Abbas *et al.*, “Compositions and methods for the treatment of immune related diseases,” 2005;
- International Publication No. WO 2006/071088 of Yoon *et al.*, “Markers for the diagnosis of AML, B-ALL and T-ALL,” 2006;
- International Publication No. EP 1487857 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” cover pages of document replaced by WO 03/080640;
- GenBank Accession No. AAH09401 GI:14424787, 2001;
- GenBank Accession No. AAH18782 GI:17511868, 2001;
- GenBank Accession No. AAS80144 GI:46095218, 2003; and
- Strausberg *et al.*, “Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequence,” *Proc Natl Acad Sci USA*, 99:16899-16903, 2002.

Also included for the Examiner’s convenience are copies of printed publications in which one or more of Applicants are co-authors. These citations have been included for the sake of completeness:

- U.S. Patent No. 6,605,280 to Novick *et al.*, “Interleukin-18 binding proteins, their preparation and use for blocking the activity of IL-18,” 2003;
- Dinarello and Kim, “IL-32, a novel cytokine with a possible role in disease,” *Ann Rheum Dis*, 65(Suppl III):iii61-iii64, 2006;
- Joosten *et al.*, “IL-32, a proinflammatory cytokine in rheumatoid arthritis,” *Proc Natl Acad Sci USA*, 103:3298-3303, 2006;
- Kim *et al.*, “Interleukin-32: A cytokine and inducer of TNF α ,” *Immunity*, 22:131-142, 2005; and
- Plater-Zyberk *et al.*, “Therapeutic effect of neutralizing endogenous IL-18 activity in the collagen-induced model of arthritis,” *J Clin Invest*, 108:1825-1832, 2001.

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: March 5, 2008

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